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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,924	10/10/2006	Mitsuru Furusawa	690116.401USPC	4614

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STOEL RIVES LLP - SLC
201 SOUTH MAIN STREET, SUITE 1100
ONE UTAH CENTER
SALT LAKE CITY, UT 84111

EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,924	FURUSAWA, MITSURU	
	Examiner	Art Unit	
	Michael Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-124* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 123 and 124 fail to comply with PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 123 and 124 are indefinite for the following reason(s):

Claims 123 and 124 provide for the use of a certain polymerases, but, since the claims do not set forth any active steps involved in the methods, it is unclear what methods applicant are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Furthermore, "use claims" are considered non-statutory under US patent practice. See MPEP § 2173.05 Therefore, the claims cannot be evaluated for restriction purposes and the claims have not been further treated on the merits.

Any amended claims will be treated as newly presented claims in the next Office Action. It will be determined at that time if they read on the elected invention.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 - 44, drawn to methods of regulating a conversion rate of a hereditary trait by regulating an error prone frequency of gene replication in the cell.

Group II, claim(s) 45 -90 , drawn to methods of producing a cell or organism having a regulated hereditary trait by regulating an error prone frequency of gene replication in the cell, then reproducing the resultant cell.

Group III, claim(s) 91 - 94, drawn to a cell or organism produced by the methods of Group II.

Group IV, claim(s) 95, drawn to a method of producing a gene having a regulated hereditary trait by changing an error prone frequency of gene replication of an organism, reproducing the resultant organism, then identifying a mutation in the organism.

Group V, claim(s) 96, drawn to a nucleic acid produced by the methods of Group IV.

Group VI, claim(s) 97, drawn to a method of producing a polypeptide having a regulated hereditary trait by changing an error prone frequency of gene replication of an organism, reproducing the resultant organism, then identifying a mutation in the organism.

Group VII, claim(s) 98, drawn to a polypeptide produced by the methods of Group VI.

Group VIII, claim(s) 99, drawn to a method of producing a metabolite of an organism having a regulated hereditary trait by changing an error prone frequency of gene replication of an organism, reproducing the resultant organism, then identifying a mutation in the organism.

Group IX, claim(s) 100, drawn to a metabolite produced by the methods of Group VIII.

Group X, claim(s) 101 - 111, 113, 114, drawn to a nucleic acid molecule comprising a sequence encoding a DNA polymerase having a regulated error prone frequency, vectors, and cells comprising the nucleic acid.

Group XI, claim(s) 112, drawn to a product substance produced by the cells of Group X.

Group XII, claim(s) 115 and 116, drawn to methods of testing a drug using a cell or organism of Group X.
Group XIII, claim(s) 117 - 122, drawn to a set of polymerases that have different error prone frequencies.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I - IX is regulating or changing the error prone frequency of gene replication in a cell (or organism). However, Morrison et al. (EMBO J., 1993, of record) teach yeast (a cell and an organism) strains comprising the *pol3-01* mutation of the *POL3* gene which, *inter alia*, is involved in 3'-5' exonuclease proofreading of gene replication errors (see Introduction and abstract, page 1467). Comparison of the mutation rate of the wild-type diploid strain and the *pol3-01/pol3-01 pms1/pms1* strain reveals a 38,000-fold difference in mutation rate (i.e. error frequency, Table I). Upon growth under selective conditions, the *pol3-01* mutant provided a number of mismatch mutations in the URA3 gene.

The technical feature linking Groups X - XII is a nucleic acid molecule comprising a sequence encoding a DNA polymerase having a regulated error prone frequency. Although it is not specifically recited in Groups I - IX, such a nucleic acid is recognized as a preferred means of providing the regulated error prone frequency of Groups I - IX, and thus provides a technical feature linking Groups X - XII to Groups I- IX. However, the yeast cells of Morrison et al (as above) were transformed with a plasmid bearing the mutant *pol3-01* mutant, i.e. an exogenous DNA polymerase (see Fig. 1, page 1467, second column, second full ¶).

Although it is not specifically recited in the broader claims of Groups I - IX, the technical feature of Group XIII (a set of polymerases that have different error prone frequencies) does appear in certain dependent claims of Groups I - IX, and thus provides a technical feature linking Group XIII to Groups I- IX. However, the yeast cells of Morrison et al (as above) comprise the mutant pol3-01 mutant and the wild type POL3, all strains had wild type POL2 and POL1, and others had a mutation in PMS1, also involved in correcting gene replication errors (see Introduction and Table I, page 1469).

Therefore, the technical feature(s) linking the inventions of Groups I - IX, Groups X - XII, and Group XIII do not constitute a special technical feature(s) as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I - XIII are not so linked by the same concept or a corresponding technical feature as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species Election I (Groups I, II and X), choose one type of polymerase, e.g. as recited in claims 13 and 14, and identify if the selection is a eukaryotic or prokaryotic polymerase;

Species Election II (Groups I and II), choose the nature of the error prone frequency modification, i.e. whether it is higher or lower as recited in claims 20 and 21 , for example;

Species Election III (Groups I, II and X), choose one of the types of cells as recited in claims 28, 29, for example. If a eukaryotic cell is chosen, then one type of eukaryotic cell as recited in claims 31 and 32, for example must also be chosen;

Species Election IV (Groups I and II), choose one of the types of cells as recited in claims 39-41, for example.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the

limitations of an allowed generic claim. Currently, the following claim(s) are generic: claims 1, 45 and 101 are generic for species election I and III, for example. Claims 1 and 45, for example, are generic for species II and IV.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit

evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633